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No. 86-842

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1986

SHILEY INCORPORATED,
Appellant,

vs.

JAMES FOGARTY CORRIGAN*, BRETT JAMES CORRIGAN,
and SCOTT GRANT CORRIGAN,
Appellees.

On Appeal from the Court of Appeal of the State of California, Second Appellate District, Division Four

MOTION TO DISMISS OR AFFIRM

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December 19, 1986

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* Brett James Corrigan and Scott Grant Corrigan, as executors of the estate of James Fogarty Corrigan, deceased, are being substituted for James Fogarty Corrigan.

QUESTIONS PRESENTED FOR REVIEW

1. Does a state appellate court order lifting a *forum non conveniens* stay order for lack of substantial evidence supporting that order rest on independent state grounds precluding review?

2. Has appellant preserved the questions sought to be reviewed where the state appellate court did not expressly decide either issue, the appellant did not appeal the denial of its motion to dismiss on grounds of *forum non conveniens,* and the appellant did not present the questions sought to be reviewed in its briefs below?

3. Does either question sought to be reviewed present a substantial federal question or a special and important reason for review given that the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976 permit the California state court action involving a California corporation which at its principal place of business in California designed, tested, manufactured and posthumously evaluated the heart valve which fractured, killing appellees' decedent?

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No. 86-842

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SHILEY INCORPORATED,
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vs.

JAMES FOGARTY CORRIGAN*, BRETT JAMES CORRIGAN, and SCOTT GRANT CORRIGAN,
Appellees.

On Appeal from the Court of Appeal of the State of California, Second Appellate District, Division Four

MOTION TO DISMISS OR AFFIRM

Appellees James Fogarty Corrigan*, Brett James Corrigan, and Scott Grant Corrigan ("Corrigans") believe that the *unanimous* decision of the California Court of Appeal to retain their wrongful death action in California should stand and, to this end, respectfully move this Court to dismiss this appeal or affirm that decision and deny the alternative petition for writ of certiorari by appellant Shiley Incorporated ("Shiley"), the California corporation which, at its principal place of business in

California, designed, manufactured, tested and evaluated the heart valve which fractured, killing their decedent Elsie Joan Corrigan. This appeal does not present any substantial federal question or any special and important reasons for review. U.S.S.CT. Rule 16.1(b),(c)&(d) (1980); U.S.S.CT. Rule 17.1 (1984). Shiley did not properly present and the court below did not expressly decide the questions sought to be reviewed. U.S.S.CT. Rule 16.1(b) (1980).

OPINION BELOW

Shiley appeals from a *unanimous* decision of the California Court of Appeal rejecting its contention that the *procedural* doctrine of *forum non conveniens* codified in CAL.CIV.PROC.CODE § 410.30(a) (1972) requires a stay or dismissal of the Corrigans' wrongful death action to permit trial in Australia. The opinion allows the Corrigans to maintain their action in the California state trial court because "[w]hen we compare the many factors weighing in favor of trial in this state against those in favor of the Australian forum, we find that the scale is tipped heavily in favor of California and that substantial evidence does not support the trial court's [stay] order." A-20.[1] The more than twenty factors balanced to reach this conclusion appear at A-6n.2.

JURISDICTION

No jurisdiction exists under 28 U.S.C. § 1257(2) (1970). Jurisdiction should not be assumed under 28 U.S.C. § 1257(3) (1970) and 28 U.S.C. § 2103 (1962).

---

[1] "A" is Appendix A to Shiley's Jurisdictional Statement and "D" is Appendix D to that document. "JA" is the Joint Appendix filed in the California Court of Appeal.

CONSTITUTIONAL PROVISIONS INVOLVED

In addition to U.S. CONST. art.I, § 8, cl.3 (1787) and U.S. CONST. art.VI, cl.2 (1787) this case involves:

U.S. CONST. amend. X (1791)

> "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States, respectively, or to the people."

This case does *not* involve U.S. CONST. art.I, § 10 (1787).

STATUTES INVOLVED

CAL.CIV.PROC.CODE § 410.30(a) (1972)

> "When a court upon motion of a party or its own motion finds that in the interest of substantial justice an action should be heard in a forum outside this state, the court shall stay or dismiss the action in whole or in part on any conditions that may be just."

In addition to 21 U.S.C. § 360k (1976) and 21 U.S.C. § 381(d) (1976), this case involves two other sections added by the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976:

21 U.S.C. § 360g(e) (1976)

> "The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law."

21 U.S.C. § 360h(d) (1976) (in part)

> "Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law."

REGULATIONS INVOLVED

21 C.F.R. § 870.3925 (1980) Replacement heart valve.

"(a) *Identification.* A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g, porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

(b) *Classification.* Class III (premarket approval)."

21 C.F.R. § 808.1 (1978) (in part)

"(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act [Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976].

* * *

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of

State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability when the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act."

STATEMENT OF THE CASE

The Fatal Heart Valve Fracture

Elsie Joan Corrigan died on September 20, 1982 in New South Wales, Australia because the outlet strut of the Bjork-Shiley mitral valve prosthesis with convexo-concave occluder disc opening to an angle of 70-degrees ("heart valve"), implanted just twelve days earlier, fractured. JA 5, 30-31, 139, 475. That heart valve was designed, manufactured, tested and posthumously evaluated by Shiley, a California corporation, at its principal place of business in California. JA 634-638, 699, 701, 704, 706, 717, 719, 722, 724. The California Court of Appeal accurately outlines her family's wrongful death action against Shiley, A-2-A-4.

Shiley Mitral Valve Prostheses With Convexo-Concave Occluder Discs Are Not "Only Exported In Foreign Commerce."

The product at issue is the Bjork-Shiley mitral valve prosthesis with convexo-concave occluder disc. Shiley makes two subcategories of these prostheses which are identical in design, manufacture, and testing except that one subcategory opens to an angle of 60-degrees and the other subcategory opens to an angle of 70-degrees. Shiley originally manufactured the 70-degree prosthesis by remilling the inlet struts on the 60-degree prosthesis. JA 84, 86, 88, 646. The outlet struts at issue are identical in design, manufacture and testing. Shiley distributes the 60-degree prostheses throughout the United States and the world. JA 22, 23, 99, 100. Shiley initiates worldwide distribution of the 70-degree prostheses in California. The relevant product is *not* "only exported in foreign commerce." "[The Corrigans] presented the trial court with ample facts as to [Shiley's] manufacture, sale and distribution of its product [in California]." A-17.

No Australians Are "Likely Responsible For the Malfunction Of the Valve."

Dr. Ross sent Elsie Corrigan's fractured heart valve to Shiley in California where it remains with at least nineteen other similarily (outlet strut) fractured heart valves. JA 19, 23, 33, 37, 78, 80, 97, 100, 134, 151, 642-664. The heart valve "autopsy" performed in California by Failure Analysis Associates at Shiley's request revealed that the side of the outlet strut which fractured first had "no evidence of an overload fracture area on this surface." JA 40-41. Whatever the risk of mishandling associated with Shiley's decision to package its heart valves in non-sterile containers knowing preimplantation sterlization is essential, this "autopsy" indicates that the outlet

strut was not damaged in Elsie Corrigan's case. Shiley has had Failure Analysis Associates "autopsy" at least thirty-one fractured heart valves implanted in eight different countries. JA 80, 87, 642-664. Studies conducted by the United States Food and Drug Administration ("FDA") and the United States Department of Health and Human Resources point to design induced manufacturing defects as the cause of the usually fatal fractures. JA 28, 50, 51, 57-58, 64, 90.

Before The Corrigans Filed A Complaint The FDA *Unilaterally Withdrew Export Approval.*

The FDA independently and *unilaterally* withdrew approval for export of the heart valves to Australia on January 11, 1983, eight months before the Corrigans filed their California state court complaint. The government of Australia played no part in that decision. The Corrigans' complaint did not and their recovery of damages could not affect that decision or Shiley's ability to export its heart valves.

The Corrigans Filed Suit In Shiley's "Home Court", The Only Forum Where They Could Obtain Personal Jurisdiction Over Shiley.

The Corrigans sued Shiley, a California corporation with its principal place of business in California, in California. They had no choice of forum. They did not forum-shop. They sued Shiley in the *only* court where they could obtain personal jurisdiction over Shiley. Thus, allowing Shiley to forum-shop by stipulating to submit to Australian jurisdiction would have little effect on any American court congestion problem because other heart valve victims would have no choice but to file suit in California to obtain personal jurisdiction over Shiley,

only to be sent away with a stipulation requiring them to file suit again elsewhere.

The Unanimous California Court of Appeal Opinion Reached A Right And Fair Result On Independent State Grounds By Balancing Many Factors, Not Just By Considering Differences In Products Liability Law.

Shiley intentionally and completely mischaracterizes the *unanimous* California Court of Appeal opinion. In balancing more than twenty factors (A-6n.2), the Court of Appeal found that CAL.CIV.PROC.CODE § 410.30(a) (1972) allowed trial in California because:

> (1) "[B]oth sides are willing to shoulder the burden of trial in the forum which is less convenient from the perspective of their respective residences, and neither forum is more convenient from the standpoint of all witnesses; therefore, this factor is essentially neutral." A-7.
>
> (2) "[T]he evidence thus far offered simply does not support a conclusion that third party negligence is a predominant or substantial issue." A-20.
>
> (3) "[A]lthough the [Corrigans'] choice of a California forum is entitled to some deference, this consideration cannot dominate our decision." A-10.
>
> (4) "Although the case cannot turn on this disadvantage in substantive law [absence of strict liability in Australia], we may permissibly consider it." A-19.
>
> (5) Shiley, the sole named defendant, is a California corporation with its principal place of business in California. This relationship imposes "an obligation to participate in judicial proceedings in the Courts of [California]". A-16.

(6) California has an important interest in regulating products manufactured in California and Australia has little interest in prohibiting a complete remedy for injury to its own citizens, whereas " 'when the defendant is a resident of California, and the tortious conduct giving rise to the wrongful death action occurs [in California], California's deterrent policy of full compensation is clearly advanced by application of its own law.' " California's comparative impairment of governmental interests choice of law rules, therefore, require choice of California law. A-14 - A-16.

(7) Trial in California would not "impose a burden 'which is unfair, inequitable or disproportionate in view of the relationship of the parties or of the cause of action to this state.' " A-17 - A-18.

Under California law a stay order not supported by substantial evidence must be lifted. *Brown v. Chlorox Co.*, 56 Cal.App.3d 306, 128 Cal.Rptr. 385 (1976).

REASONS FOR DISMISSING THE APPEAL OR AFFIRMING THE UNANIMOUS ORDER AND REFUSING TO ISSUE A WRIT OF CERTIORARI

I.

THE *UNANIMOUS* ORDER MAY NOT BE REVIEWED BY APPEAL OR CERTIORARI BECAUSE IT RESTS ON ADEQUATE AND INDEPENDENT STATE GROUNDS—CAL.CIV.PROC. CODE § 410.30(a) (1972).

The California Court of Appeal unanimously reversed a trial court stay order based on California's statutory doctrine of *forum non conveniens*. A-1. The doctrine of *forum non conveniens* raises a procedural question of state

law. CAL.CIV.PROC.CODE § 410.30(a) (1972); *Price v. Atchison, Topeka & Santa Fe Railway Co.*, 42 Cal.2d 577, 581-582, 268 P.2d 457 (1954). The order rests on an adequate non-federal basis; therefore, dismissal is appropriate. U.S.S.CT. Rule 16.1(b) (1980). It is not the function of this Court to construe a state statute contrary to the construction given to it by the highest court of the State. *O'Brien v. Skinner*, 414 U.S. 524, 531 (1974); *California v. Ramos*, 463 U.S. 992, 1010 n.24 (1983). Shiley does not urge any due process violation under U.S. CONST. amend. XIV, § 1, cl. 3 (1868). A state court order based on adequate and independent state grounds may not be reviewed by appeal or certiorari. *Wolfe v. North Carolina*, 364 U.S. 177, 179 n.3 (1960).

II.

THE UNANIMOUS ORDER MAY NOT BE REVIEWED BY APPEAL OR CERTIORARI BECAUSE THE FEDERAL QUESTIONS SOUGHT TO BE REVIEWED WERE NOT TIMELY OR PROPERLY RAISED BELOW, HENCE NOT EXPRESSLY DECIDED.

Shiley concedes that the court below did not expressly pass on the questions sought to be reviewed. Jurisdictional Statement at 2 n.3. "[W]hen 'the highest state court has failed to pass upon a federal question, it will be assumed that the omission was due to want of proper presentation in the state courts. . . .'" *Exxon Corp. v. Eagerton*, 462 U.S. 176, 181 n.3 (1983).

> "Even if . . . not jurisdictionally barred from considering claims not pressed or passed upon in the state court . . ., the longstanding rule that this Court will not consider such claims creates, at the least, a weighty presumption against review."

Heath v. Alabama, 474 U.S. ____, 88 L.Ed.2d 387, 393 (1985).

The trial court properly denied Shiley's motion to dismiss the Corrigans' action. D-1; *Brown v. Chlorox Co.*, 56 Cal.App.3d 306, 313-314, 128 Cal.Rptr. 385 (1976). Shiley did *not* appeal that denial.

On its own motion the trial court stayed the Corrigans' action under CAL.CIV.PROC.CODE § 410.30(a) (1972) and the Corrigans appealed. In its Respondent's Brief Shiley cited no federal constitutional provisions, statutes or regulations. Shiley did not raise or brief the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976, P.L. 94-295 (1976).

Shiley did not argue that "federally-established forum non conveniens doctrine is binding on state courts in litigation arising from foreign commerce exports." Shiley just asked the Court of Appeal to reject *Holmes v. Syntex Laboratories, Inc.*, 156 Cal.App.3d 372, 202 Cal.Rptr. 773 (1984), *petition for hearing denied,* August 22, 1984. Respondent's Brief at 46. The California Court of Appeal responded, holding:

> "Under California law, the purpose of comparing the differences in conflict of law rules and the differences in substantive law which will be applied, once the choice of law has been made in each alternative forum, is not simply to decide which forum would provide the most advantageous law from the viewpoint of the plaintiff. To the extent *Holmes* explicitly or implicitly directs otherwise, we decline to follow it." A-12.

Shiley did not argue that any specific federal powers mandated dismissal. To quote Shiley: "At the least, principles of comity strongly suggest that California should

defer to Australian law in the trial of this action." Respondent's Brief at 39-40.

Shiley's Petition for Rehearing cites no federal constitutional provisions, statutes or regulations. It does not even cite *Piper Aircraft Co. v. Reyno,* 454 U.S. 235 (1981) or *Japan Line, Ltd. v. County of Los Angeles,* 441 U.S. 434 (1979).

Shiley's Petition for Review to the California Supreme Court also fails to cite any federal constitutional provisions, statutes or regulations. Its issues presented for review are:

> "(1) Does a trial court have discretion to stay on the ground of forum non conveniens an international wrongful death/products liability action brought by Australian plaintiffs against a California resident manufacturer?
>
> (2) Should a governmental interest and comparative impairment choice of law analysis, when raised in the context of a forum non conveniens determination in a wrongful death/products liability action brought by foreign plaintiffs, consider the broader social policies advanced by the law of the foreign state — such as fostering the availability of needed high-technology medical products imports for its residents — or should it focus only on the foreign state's interest in the immediate recovery of its resident plaintiffs?"

Petition for Review at 1.

Not until receiving Shiley's Jurisdictional Statement did the Corrigans know which constitutional provisions Shiley would urge. Shiley did not specifically and plainly argue that CAL.CIV.PROC.CODE § 410.30(a) (1972), as applied to Shiley, violated federal law; rather, Shiley argued that trial of the Corrigans' action in California

would deprive Shiley of unspecified federal constitutional rights as a product exporter. Under these circumstances appeal is not proper. *Calder v. Jones,* 465 U.S. 783, 787-788 n.7 (1984). "It is not enough that there may be hidden in the record a question which, if it had been raised, would have been of a Federal nature." *Whitney v. California,* 274 U.S. 357, 362 (1926). Because Shiley did not timely and properly raise the issues now sought to be reviewed so the courts below did not expressly decide the issues, Shiley's appeal should be dismissed. U.S.S.CT. Rule 16.1(b) (1980). For the same reason, a writ of certiorari should not issue.

III.

BECAUSE THE FEDERAL FOOD, DRUG, AND COSMETIC ACT MEDICAL DEVICE AMENDMENTS OF 1976 SPECIFICALLY PERMIT STATE WRONGFUL DEATH ACTIONS NO CONSTITUTIONAL VIOLATIONS EXIST.

In the area of preemption "each case turns on the peculiarities and special features of the federal regulatory scheme in question." *City of Burbank v. Lockheed Air Terminal,* 411 U.S. 624, 638 (1973). It is not the practice of this Court to reach out to decide constitutional issues where none exist. *Rice v. Sioux City Memorial Park Cemetery, Inc.,* 349 U.S. 70, 74 (1955).

A. Deaths Caused by Heart Valves Prompted Enactment of the Medical Device Amendments of 1976.

Deaths caused by prosthetic heart valves are one major reason for passage of the Medical Device Amendments of 1976, P.L. 94-295 (1976). As Senator Gaylord Nelson noted:

> "Heart valves. Changes in the materials or components that were inadequately tested resulted in serious failures of parts of certain heart valves, including one model that had a failed strut. Four deaths have been attributed to this failure. More thorough premarket testing would have shown up such problems."

122 CONG.REC. 10690 (1975).

Dr. Theodore Cooper, Director of the National Heart and Lung Institute, headed a panel which searched the scientific literature for accounts of injuries from medical devices and, in 1970, reported to Congress 512 deaths and 300 injuries attributed to heart valves. S.REP.NO. 94-33, 94th Cong., 2d Sess. 5, *reprinted in* 1976 U.S. CODE CONG. & AD.NEWS 1070, 1075. *See, e.g., Gill v. Surgitool, Inc.,* 256 Cal.App.2d 583, 584, 64 Cal.Rptr. 207 (1967); *In Re Cutter Laboratories, Inc. "Braunwald-Cutter" Aortic Heart Valve Products Liability Litigation,* 465 F.Supp. 1295 (J.P.M.L.1979).

B. The Federal Food, Drug, and Cosmetic Act Does Not Bar State Wrongful Death Actions.

The Federal Food, Drug, and Cosmetic Act does not create a private right of action for individuals injured as a result of violation of the Act. *Merrell Dow Pharmaceuticals, Inc. v. Thompson,* 474 U.S. ___, 92 L.Ed.2d 650, 660 (1986) (*forum non conveniens* dismissal of products liability action by foreign plaintiffs against Ohio Bendectin manufacturer reversed because removal improper). Since 1938 state common law and statutory remedies have redressed violations of the Act. Cole & Shapiro, *Private Litigation Under The Federal Food, Drug, and Cosmetic Act: Should the Right To Sue Be Implied?* 30 FOOD, DRUG & COSM. L.J. 576, 578 (1975). *See, e.g., Toole v.*

Richardson Merrell, Inc., 251 Cal.App.2d 689, 60 Cal.Rptr. 398 (1967). *See generally*, P.L. 87-781, § 202 (1962), *reprinted in*, Note, 21 U.S.C.A. § 321 at 128-129. This Court has already expressly determined that, at least insofar as public safety is concerned, the action of a state civil jury in awarding compensatory damages does not impermissibly interfere with a federal agency's regulatory jurisdiction. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984). "There is no element of regulation when compensatory damages are awarded . . . ." 464 U.S. 276 n.3 (Powell et al. dissent).

> "Whatever compensation standard a State imposes, whether it be negligence or strict liability, a licensee remains free to continue operating under federal standards and to pay for the injury that results. This is presumably what Congress had in mind when it preempted state authority to set administrative standards but left state compensatory schemes intact."

464 U.S. 264 (Blackmun & Marshall dissent).

C. Preemption Of State Law Under The Medical Device Amendments of 1976 Is Very Limited And Does Not Bar The Corrigans' Action Against Shiley.

The Medical Device Amendments of 1976 contain at least five savings clauses preserving states' rights. Under 21 U.S.C. § 360g(e) (1976) "[t]he remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law." Under 21 U.S.C. § 360h(d) (1976) "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law." Under 21 U.S.C. § 360k(a)(1) (1976) a State may "establish or continue in effect with respect to a device . . . any requirement" that is not "different from, or in addition to" any applica-

ble requirement of the Act, *i.e.*, "equal to, or substantially identical to" requirements are not preempted. 21 C.F.R. § 808.1(d)(2) (1978). This provision clearly permits state wrongful death actions based on negligence per se violations of federal or identical state requirements. *See, e.g., Toole, supra,* at 697, 701 & 702-704. Under 21 U.S.C. § 360k(b) (1976) a state may also obtain exemptions.

The FDA has issued final rules on the scope of federal preemption under 21 U.S.C. § 360k (1976). 43 Fed.Reg. 18,661 (1978). The relevant portions of 21 C.F.R. § 808.1 (1978) state that 21 U.S.C. § 360k (1976) does not preempt (1) general requirements like the U.C.C. warranty of fitness for a particular purpose or (2) requirements essentially identical to federal law or (3) requirements not "applicable to a device". "Thus, as a general proposition, state prohibitions against sale of adulterated or misbranded devices are not preempted." 43 Fed.Reg. 18,663 (1978). Moreover, 21 C.F.R. § 808.1(d) (1978) states that under 21 U.S.C. § 360k (1976) "[s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements." "There is nothing in the legislative history to indicate Congress intended that the Amendments should result in less protection for the public." 43 Fed.Reg. 18,663 (1978).

Elsie Joan Corrigan received her heart valve on September 8, 1982 and died twelve days later. At the very earliest FDA regulations required submission of preliminary applications for premarket approval on September

30, 1982. 45 Fed.Reg. 7948 (1980). The FDA final rules on premarket approval of medical devices under 21 U.S.C. § 360e (1976) did not become effective until *November 19, 1986.* 51 Fed.Reg. 26,342-26,372 (1986). Those rules revoked any prior inconsistent approvals. 51 Fed.Reg. 26,343 (1986). One purpose of 21 U.S.C. § 360e (1976) now stated in 21 C.F.R. § 814.2(b) (1986) is "[t]o ensure the disapproval of premarket approvals for devices that have not been shown to be safe and effective or that do not otherwise meet statutory criteria for approval." 51 Fed.Reg. 26,365 (1986). Thus, under 21 C.F.R. § 808.1(a) (1978) when Elsie Corrigan died no specific FDA regulations existed so all California requirements relative to Shiley's heart valves remained in effect.

"Briefly, from a plain reading of section 521 of the Act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices." 45 Fed.Reg. 67,321 (1980). "The FDA position will not cause an undue burden on interstate commerce because it merely allows State and local requirements to continue in effect until FDA establishes a national policy on the regulation of specific devices." 45 Fed.Reg. 67,322 (1980). "In fact, Congress specifically cited the California Sherman Food, Drug, and Cosmetic law . . . as the type of requirements that should be permitted to continue in effect." 45 Fed.Reg. 67,322 (1980); H.R. REP. NO. 94-853, 94th Cong., 2d Sess. 46 (1976). "[T]he construction of a statute by those charged with its administration is entitled to substantial deference." *United States v. Rutherford,* 442 U.S. 544, 553 (1979).

D. Neither U.S. CONST. art. I, § 8, cl. 3 (1787) Nor U.S. CONST. art. VI, cl. 2 (1787) Bar This Action.

"[T]he dormant Commerce Clause, in both its interstate and foreign incarnations, only operates where the Federal Government has not spoken to ensure that the essential attributes of nationhood will not be jeopardized by States acting as independent economic actors. However, the Federal Government is entitled in its wisdom to act to permit the States varying degrees of regulatory authority." *Wardair Canada, Inc. v. Florida Dept. of Revenue,* 477 U.S. ____, 91 L.Ed.2d 1, 12 (1986). Thus, U.S. CONST. art. I § 8, cl. 3 (1787) does not bar the Corrigans' action against Shiley. For parallel reasons, U.S. CONST. art. VI, cl. 2 (1787) does not preclude it. California law, the Medical Device Amendments of 1976 as interpreted by the FDA, and U.S. CONST. amend. X (1791) permit the Corrigans to bring their action against Shiley in California.

IV.

THE CALIFORNIA COURT OF APPEAL'S UNANIMOUS DECISION TO RETAIN THE CORRIGANS' ACTION AGAINST SHILEY IN CALIFORNIA DID NOT WRONGLY DECIDE ANY FEDERAL QUESTION.

A. Before The Corrigans Filed Their Complaint The FDA Independently And Unilaterally Banned Export Of Shiley's Heart Valves Under 21 U.S.C. § 381(d)(2) (1976) Because These Heart Valves Posed A Threat To Public Health And Safety.

Under 21 U.S.C. § 381(d)(2) (1976) a medical device may not be exported unless the FDA has unilaterally

determined that "exportation of the device is not contrary to public health and safety." The Senate Labor and Public Welfare Committee clearly stated:

> "The Committee does not believe that substandard or unsafe or ineffective devices should be permitted to be exported to foreign nations and has thus provided in its bill that the Secretary may deny export of any devices which do not fully conform to the provisions of this Act.... The Committee has ... provided in this section of the bill that such articles may be exported to foreign countries where the Secretary finds that the non-compliance is not of such a nature as to expose the populations of foreign countries to undue risks of the public health...."

S.REP.NO. 94-33, 94th Cong., 2d Sess. 18, *reprinted* in 1976 U.S. CODE CONG. & AD. NEWS 1070, 1087. The bill enacted adopted this approach. H. CONF. REP. NO. 94-1090, 94th Cong., 2d Sess. 66, *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS 1070, 1118.

> "As of [1983], on only two occasions [had the] FDA prohibited the export of a device on the basis that it is contrary to the public health and safety. Both of these occasions involved heart valves. Export was denied because of questions about the safety or effectiveness of the valves."

Stigi et al., *The Food and Drug Administration's Policy in Relation to the Exportation of Medical Devices,* 38 FOOD, DRUG & COSM. L.J. 193, 196 (1983). The FDA unilaterally revoked Shiley's export permit on January 1, 1983 because:

> "Your firm's hypothesis that surgeon error is the cause of the two (2) Australian failures ... lacks any technical support at this time.

* * *

> Until such time as you are able to show that the problem is not inherent to the valve itself, we cannot allow further shipments under § 801(d) of the Federal Food, Drug and Cosmetic Act." JA 86.

Under these circumstances the Corrigans' action against Shiley in California did have and could have no impact on the availability or affordability of innovative medical devices imported into Australia from the United States. Congress clearly intended in enacting 21 U.S.C. § 381(d)(2) (1976) that social policies of foreign governments be subservient to public morality and the integrity of the "Made in the U.S.A." label.

B. Foreign Governments Rely On U.S. Regulatory Agencies To Determine The Safety Of Exported Medical Devices; Therefore, Requiring Shiley to Defend Itself In Its "Home Court" Will Not Create Any Unwarranted Interference With Australian Public Policy.

> "The sophistication of modern medical devices makes careful testing necessary to determine if a device operates safely and as claimed. . . . Many devices are so intricate that skilled health professionals are unable to ascertain whether they are defective. Increasing numbers of patients have been exposed to increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used."

S.REP. NO. 94-33, 94th Cong., 2nd Sess. 6, *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS 1070, 1075. Thus, foreign governments, particularly those of underdeveloped nations, rely on decisions and determinations of

U.S. regulatory agencies. H.R. REP. NO. 95-1686, 95th Cong., 2d Sess. 5 (1978). Dumping by U.S. firms poses a major problem for these countries. *Drug Regulation Reform Act of 1978: Hearings Before the Subcomm. on Health & Environment, House Comm. on Interstate and Foreign Commerce,* 95th Cong., 2d Sess. 1322, 1326 (1978). Foreign governments need greater U.S. help in evaluating advanced technology. *Id.* at 1330-1335. In New Zealand, for example, the Department of Fisheries authorizes importation of porcine heart valves. Stigi et al., *supra,* 198. American high technology exports are not independently evaluated by other nations, including Australia, which lack the money and sophisticated manpower required. "[M]ere governmental approval or foreign government involvement which the defendant had arranged does not provide a defense." *Timberlane Lumber Co. v. Bank of America, N.T.&S.A.,* 549 F.2d 597, 606 (9th Cir. 1976).

C. Extraterritoriality Is Not At Issue; Therefore, Requiring Shiley To Defend Itself In California Will Not Offend Any Principles of International Comity.

Problems of extraterritoriality have arisen between Australia and the United States primarily with respect to America's efforts to impose its antitrust laws on the activities of Australian companies outside of the Unites States and also with respect to efforts by Australians to subject Australian operations of American companies to American environmental protection laws. *Transcript of a White House Press Briefing, June 30, 1981, Discussion Between President Reagan and Australian Prime Minister Fraser,* AMERICAN FOREIGN POLICY CURRENT DOCUMENTS 1981, Document 485, U.S. Dept. of State Pub. No. 9384 (1984). Extraterritoriality does not exist here because Shiley is a California corporation which designed, tested, manufactured and posthumously evalu-

ated Elsie Corrigan's heart valve at its principal place of business in California. Even a foreign sovereign would be subject to jurisdiction under these circumstances. 28 U.S.C. § 1605(a)(2) (1976). "Purely commercial activity ordinarily does not require judicial forebearance under the act of state doctrine." *Northrop Corp. v. McDonnell Douglas Corp.,* 705 F.2d 1030, 1048 n.25 (9th Cir. 1983), *cert. denied,* 464 U.S. 489 (1984); *Williams v. Curtis-Wright Corp.,* 694 F.2d 300, 304 (3d Cir. 1982). Surely California may hold Shiley responsible for its activities in California. U.S. CONST. amend. X (1791).

D. Requiring Shiley To Defend Itself In Its Home Court Will Not Create Any Substantial Threat To American Export Policy.

The FDA banned export of Shiley's heart valves under 21 U.S.C. § 381(d)(2) (1976) before the Corrigans filed suit; therefore their complaint for compensatory damages for wrongful death did not create Shiley's inability to export its heart valves. Theoretically, the power to ban export of medical devices which threaten public health and safety which Congress gave the FDA in the Medical Device Amendments of 1976 might inhibit development and export of such devices. Report of the President's Commission on Industrial Competitiveness, *Global Competition: The New Reality,* Vol II, 283-284 (1985). In fact, a survey conducted for the FDA in 1982 found "no evidence that the Medical Device Amendments have introduced barriers to market entry, reduced innovation in the industry, or adversely affected investments, sales or employment." Stigi et al., *supra,* 193.

Of course, the Corrigans' tort recovery raises an independent issue. Shiley cites no authority identifying damages paid to victims of medical devices as a cause for concern or recommending any related change in products

liability laws. The authorities Shiley does cite indicate that any impairment may be self-inflicted. "A firm is competitive if it can produce products . . . of superior quality . . . than its domestic or international competitors." II *Global Competition* 6 (1985). Managerial incentives and techniques have caused American firms to underfund research and development projects with long-term economic and social benefits, thereby reducing the competitiveness of their products. *An Assessment of U.S. Competitiveness In High Technology Industries,* U.S. Dept. of Commerce Int'l Trade Admin. 23 (1983). "A heart valve . . . is intended to remain in the body for an extended period of time and to function autonomously within the body." Posner, *Implantable Medical Devices & Products Liability*, 36 FOOD, DRUG & COSM. L.J. 622, 625-626 (1975). Mrs. Corrigan's heart valve lasted just twelve days. The quality of Shiley's heart valve, not the Corrigans' wrongful death action, is the cause of any export difficulties.

Adhering to one's own moral code is not "sadly paternalistic". Principles of international comity require Australia to respect the public morality reflected in the Medical Device Amendments of 1976. This view remains valid.

Subsequent to U.S. export of carcinogenic TRIS infant sleepwear the Subcommittee on Commerce, Consumer and Monetary Affairs of the House Committee on Government Operations held hearings on U.S. export of products banned by U.S. regulatory agencies and concluded that the U.S. must accept responsibility for what it exports, including notifying foreign countries of hazards and unilaterally banning export of unreasonably dangerous products. H.R. REP. NO. 1686, 95th Cong., 2d Sess. 3 (1978). The Subcommittee on International Economic Policy and

Trade of the House Committee on Foreign Affairs reached similar conclusions. *Export of Hazardous Products: Hearing Before the Subcomm. On Int'l Econ. Pol'y and Trade. House Comm. on Foreign Aff.*, 96th Cong., 2d Sess. 23-24 and 27-28 (1980). The Medical Device Amendments of 1976 grant the FDA such authority.

Aliens have historically been allowed access to U.S. courts to foster trade relations. Bator et al., HART & WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM (2d ed. 1973). Allowing the Corrigans to maintain their action against Shiley in the California state courts is consistent with this view of American foreign policy.

V.

THE ALLEGED CONFLICTS ARE IRRELEVANT.

Shiley cites no conflicting decisions by state courts of last resort. Jurisdictional Statement at 8 n.9. Because the doctrine of *forum non conveniens* raises an independent and adequate state ground for the California Court of Appeal decision any difference between that unanimous decision and *Piper Aircraft Co. v. Reyno*, 454 U.S. 235 (1981), *rehearing denied*, 455 U.S. 928 (1982) and its federal progeny is not a "conflict with applicable decisions" supporting review under U.S.S.CT. Rule 17.1(b) or (c) (1984).

In *Piper* this Court only held that a defendant is not entitled to dismissal on grounds of *forum non conveniens* solely because the law of the original forum is less favorable to it than the law of its chosen alternative forum and that a plaintiff cannot defeat the defendant's motion merely by showing that the law of the original forum is more favorable to them. 454 U.S. 246 n.12, 247 & 252 n.19.

The court below agreed. A-12. (*Holmes,* if contrary, is not on appeal here.) In *Piper* this Court did "not hold that the possibility of an unfavorable change in law should *never* be a relevant consideration in a *forum non conveniens* inquiry." 454 U.S. 254. The court below actually held that "[a]lthough the case cannot turn on this disadvantage in different substantive law, we may permissibly consider it." A-19. Thus, the only possible "conflict" would be the weight given to that factor under the circumstances of this case.

In *Piper* this Court retained the balancing test set forth in *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501 (1947) but only four justices agreed that the district court had not abused its discretion by dismissing the action. 454 U.S. 261 & 262. The court below held that under California law the trial court's stay order was not supported by substantial evidence based on consideration of more than twenty factors to be balanced under CAL.CIV.PROC.CODE § 410.30(a) (1972). A-6n.2 & A-20. Even if *Piper* were controlling and the court below did give undue weight to the absence of strict liability in Australia, adjusting that weight and rebalancing the many relevant factors would not be likely to produce a different result on remand. Any such conflict with *Piper* does not merit review under U.S.S.CT. Rule 17.1(c) (1984).

CONCLUSION

No amount of rhetorical manipulation by Shiley can transform this case into something it decidedly is not: a case properly presenting a substantial federal question worthy of review by this Court. For the reasons stated above, the Corrigans respectfully submit that this appeal should be dismissed or the unanimous decision below should be affirmed and no writ of certiorari should issue.

DATED: December 19, 1986.

Respectfully submitted,

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PROOF OF SERVICE BY MAIL

I am a citizen of the United States and a resident of the City and County of Los Angeles; I am over the age of eighteen years and not a party to the within action; my business address is: 1706 Maple Avenue, Los Angeles, California.

On December 19, 1986, I served the within Motion to Dismiss or Affirm in re: "Shiley Inc. -v- James Fogarty Corrigan" in the United States Supreme Court, October Term, 1986, No. 86-842;

on the Parties in said action, by placing 3 copies thereof enclosed in a sealed envelope with postage fully prepaid, in the United States post office mail box at Los Angeles, California, addressed as follows:

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All Parties required to be served have been served.

I certify (or declare), under penalty of perjury, that the foregoing is true and correct.

Executed on December 19, 1986, at Los Angeles, California

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